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Rehabilitation and Reintegration Programming Following Female Genital Fistula Surgery: A Scoping Review Protocol

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Keywords:	female genital fistula, supportive care, reintegration, rehabilitation, scoping review

SCHOLARONE[™] Manuscripts

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Abstract

Introduction

Female genital fistula is a debilitating and traumatic injury, largely birth-associated, globally affecting as many as 2 million women, mostly in sub-Saharan Africa. Fistula is associated with significant physical, psychological, and economic consequences. Women often face challenges in reintegrating and resuming their prior roles despite successful surgery. Synthesizing the evidence on services adjunct to fistula surgery and their outcomes is important for developing a strong evidence base to guide service provision and identifying additional research priorities. The objective of this scoping review is to examine the range of rehabilitation and reintegration services provided as adjunct to genital fistula surgery, map the existing programming and outcomes, and identify areas for additional research.

Methods and analysis

Our scoping review is informed by existing methodological frameworks and will be conducted in accordance with PRISMA-ScR guidelines. The search strategy will be applied to nine biomedical, public health, and social science databases. Grey literature will be identified through targeted Google searches and from organizational websites identified as relevant by the UNFPA Campaign to End Fistula. We will iteratively build our search strategy through term harvesting and review, and search reference lists of reports and articles to identify additional studies. Two reviewers will independently screen titles and abstracts, followed by full-text screening of all potentially relevant articles and standardized data extraction. Articles eligible for inclusion will discuss research or programmatic efforts around service provision in adjunct to surgery among females with genital fistula. Data will be presented in summary tables accompanied by narrative description.

Ethics and dissemination

Ethics approval is not required for a scoping review. Our results can be used to inform policy, serve as support for funding and development of reintegration programs, and highlight areas for subsequent research. The results will be presented at relevant international conferences and published in a peer-reviewed journal.

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Article Summary:

- 1. No systematic efforts have been previously carried out to map the rehabilitation and reintegration services provided in adjunct to female genital fistula surgery despite recognition in the literature of significant physical, psychosocial, and economic sequelae of the condition.
- 2. Our scoping review utilizes an established framework, employs a comprehensive search strategy developed iteratively in conjunction with a medical librarian, and study selection and extraction will be undertaken by content experts.
- 3. Compiling the evidence on existing programs and outcomes will inform the development of evidence-based public health strategies for supporting women recovering from female genital fistula and inform the measurement of impact of such strategies.
- 4. No formal assessment of the quality of studies will be conducted, as the goal of a scoping review is to map the range of evidence on a particular topic.
- 5. The findings of this scoping review will be limited to articles and program reports published in English or French.

Keywords: female genital fistula, supportive care, reintegration, rehabilitation, scoping review

Introduction

Female genital fistula is a debilitating and traumatic injury that affects an estimated 2 million women, mostly in sub-Saharan Africa¹. Primarily due to prolonged and neglected obstructed labor from cephalopelvic disproportion or malpresentation combined with delays in accessing comprehensive emergency obstetric care, up to 100,000 new cases occur each year globally. During the obstructed labor, ischemia from compression of soft vaginal, bladder or rectal tissue between the fetal head and pelvic bone results in ischaemic necrosis, and a fistula is formed upon sloughing of this tissue². Women with fistula experience uncontrollable leakage of urine and/or feces, which contributes to the development of genital sores and infection ^{3,4}. In addition to pain and general weakness⁵, women may experience nerve damage, uterine cervix injuries and pelvic bone trauma which present as secondary infertility and gait disorders⁶. For most deliveries resulting in fistula, the baby does not survive⁷. Women with fistula are often stigmatized and marginalized from their families and communities and live in isolation, unable to participate in social, economic, food preparation or religious activities^{5,7}, and report high psychiatric morbidity including depression, which may persist after surgery⁸⁻¹⁰.

Access to obstetric fistula surgery has improved in sub-Saharan Africa overall; however, despite having undergone surgical repair, women may continue to face myriad physical and psychological challenges to resuming their previous roles or adjusting to new circumstances. They may also require further medical care depending on the severity of their injuries and surgical outcomes and require health care access for subsequent pregnancies and births. Longitudinal studies from sub-Saharan Africa have identified risks of adverse outcome following fistula surgery, including fistula recurrence, persistent fistula-related symptoms, subsequent fertility challenges, and adverse perinatal outcomes¹¹⁻¹³. In Guinea, for example, the cumulative incidence of fistula recurrence was 16% at 24 months¹³. In Uganda, by twelve-months post-surgery, one-third of women continued to experience urinary incontinence, 17% reported weakness, and 9% reported general pain¹⁴. In Malawi, only one-fifth of women with reproductive potential were able to become pregnant in the year following surgery¹². Furthermore, experience of persistent physical symptoms or adversity is associated with substantially lower psychosocial health¹⁴. All of these factors limit women's ability to resume their previous roles despite successful surgery, particularly in the context of economic hardship¹⁵. A systematic review of ten gualitative studies from sub-Saharan Africa identified various reintegration needs from the perspectives of both women affected by fistula and health professionals working with this patient population, including health education and counselling¹⁶.

This literature highlights the need for post-surgical reintegration and rehabilitation services; however, there remains a knowledge and practice gap around programming to best assist women to reintegrate into their families and communities after surgery. Preliminary evidence from Nigeria and Eritrea supports short-term facility-based psychological intervention for improving women's mental health^{17,18}, and programming supported by non-governmental organizations often includes counseling, physical therapy, and skills training. Synthesizing research on the reintegration process, evaluation, and service provision is of paramount importance to develop a strong evidence base, which can guide prioritization of service provision to meeting the future health needs of women who have experienced obstetric fistula.

Thus, the objective of this scoping review is to examine the range of rehabilitation and reintegration services provided as adjunct to genital fistula surgery, map the existing programming and outcomes, and identify areas where additional research is necessary.

Methods and analysis

The purpose of this scoping review is to understand the extent to which rehabilitation and reintegration services have been provided to women in conjunction with female genital fistula surgery and the outcomes of such programming. The findings from this review will be used to support the evidence-based development of programming for women undergoing surgery for female genital fistula surgery and identify further research needs in this area. A preliminary search for existing reviews on this topic has been conducted in JBISIR, PROSPERO, PubMed, Cochrane Database of Systematic Reviews, EPPI, and Epistemonikos, and no similar systematic or scoping reviews were identified. Given the lack of prior reviews, a scoping review is an appropriate first step to assessing the literature in this area. Our scoping review methodology is informed by the Arskey & O'Malley¹⁹ and Levac²⁰ frameworks and will be conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-ScR) guidelines.²¹

Identifying the Research Question

The objective of this scoping review is to examine the range of rehabilitation and reintegration services provided as adjunct to genital fistula surgery, map the existing programming and outcomes of programming, and identify areas where additional research is necessary. To achieve these objectives, our review targets the following research questions:

- 1. What rehabilitation and reintegration services are provided as adjunct to genital fistula surgery for women with obstetric, iatrogenic, or traumatic fistula?
- 2. What are the components of each rehabilitation and reintegration intervention, and how are they delivered?
- 3. What is the impact of each rehabilitation and reintegration intervention on women's physical, psychosocial, and economic status?
- 4. What are the authors' recommendations for rehabilitation and reintegration interventions and intervention delivery?

In this review, we include genital fistula from obstetric, iatrogenic, and traumatic etiologies. Obstetric refers to fistula resulting from pressure necrosis due to prolonged obstructed labor; iatrogenic refers to fistula resulting from surgical error, primarily occurring during cesarean section or hysterectomy; and traumatic refers to those fistula resulting from sexual assault.

Types of Sources

Sources to be reviewed include biomedical, public health, and social science databases, including PubMed, Embase, Popline, PsycINFO, Web of Science, Sociological Abstracts, Social Services Abstracts, and African Journals Online, the grey literature identified within targeted Google searches and directly from organization websites identified as being relevant by the Campaign to End Fistula Partners (UNFPA) (Appendix 1), and through personal queries with clinical and social service organizations working in fistula research.

Search Strategy

We will employ a three-step search strategy for identifying published and unpublished studies for our scoping review.

We will begin by conducting a preliminary search of PubMed to identify key articles on our topic and begin the process of term harvesting, described herein. From these key articles, we will extract text words and MeSH terms from titles, abstracts, and author-supplied keywords to build a comprehensive list of keywords and controlled vocabulary terms, to inform our search strategy development. Next, we will work collaboratively with a medical librarian (JBW) with training and experience in systematic reviews to design

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our search strategy using an iterative process that follows an established search method²². Each potential search term will be tested, with the two primary reviewers examining the first 60 unique results for each term in order to determine that term's relevance and subsequent inclusion in the search strategy. The search strategy will be developed in PubMed and adapted to other databases accordingly, using controlled vocabulary (e.g. MeSH, Emtree, thesaurus terms) where databases allow. A second librarian will peer review the final search strategy using the Peer Review of Electronic Search Strategies (PRESS) guidelines.²³

Thirdly, the reference lists of all included reports and articles will be searched to identify any additional studies. The reviewers will contact authors of primary studies, reviews, and grey literature if further information is desired.

The search strategy will combine two main concepts: obstetric fistula and social reintegration. Boolean logic will be applied by combining similar key words and controlled vocabulary (e.g. MeSH and Emtree terms) with OR and using AND between the two concepts, for example, ("obstetric fistula" OR "vesicovaginal fistula") AND (reintegration OR rehabilitation). During preliminary searching, we have found a large number of, irrelevant articles related to cancer in two sets of database 31% of our results in Embase and 17% of our results in Web of Science); therefore, an additional concept using cancer-related terms will be added using the NOT term that will exclude these terms from our searches in those two databases. To ensure that this concept exclusion will not eliminate any relevant results, the primary reviewers evaluated the first 100 unique results that would be left out of searches that used this NOT concept. No relevant articles were discovered using this method; thus, we feel confident that this technique will only exclude irrelevant articles. The complete search strategy for all databases can be found in Appendix 2.

In accordance with PRISMA guidelines, no language limits will be used in the search. Date limits will be applied to identify relevant studies as social reintegration for obstetric fistula is a new area of study. To determine which date limits to use, primary reviewers tested searches from various publication date ranges, looking through the first 50 unique results of each time span to judge relevance of the studies included in these dates. Using this method, we chose to include articles from 2000 to the present.

Study selection

Two primary reviewers (AE & CP) will independently screen titles and abstracts of all articles, followed by full-text screening and data extraction. A third reviewer (AD) will be available to resolve discrepancies. Study screening progress will be documented in a modified PRISMA flow chart (Figure 1). In accordance with established scoping review frameworks,^{19,20} critical appraisal of study quality will not be performed owing to the heterogeneity of results and the multi-tiered aspect of the research question.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for selection of eligible studies were developed using the population, concept, context elements proposed for scoping reviews by the Joanna Briggs Institute (Table 1).²⁴ We selected this approach in order to broadly identify all data that is potentially relevant to our objective.

Types of participants

Females diagnosed with genital fistula with obstetric, iatrogenic (non-cancer), or traumatic etiology and accessing surgical treatment. No limitations on geography or age will be placed.

Concept

Research or service provision for all services provided in adjunct to surgery among females diagnosed with genital fistula of obstetric, iatrogenic (non-cancer), or traumatic etiology. Interventions of interest are anticipated to include, but will not be limited to the following: psychological therapy, physical therapy, skills training or other economic empowerment.

The scoping review will be heavily focused on the services provided; however, we will capture any clinical or patient-reported outcomes beyond surgical success including but not limited to: persistent incontinence, pain, weakness, difficulty walking, quality of life, depressive symptoms, self-esteem, relationship stability, and stigma.

Context

No contextual limitations will be placed on the scoping review; however, we are unable to review articles written in languages other than English and French. Due to the geographic distribution of female genital fistula, we anticipate that the majority of the evidence will originate in sub-Saharan Africa.

Table 1. Population, Concept, Context for Identification of Eligible Studies

Criteria	Description
Population	Females undergoing surgery for genital fistula
	Fistula etiologies: obstetric, iatrogenic (non-cancer), traumatic
	All ages
Concept	Any research or service provision in addition to surgery; no limitations on intervention
	type
	Clinical or patient-reported outcomes beyond surgical success
	Studies or reports including original research or program data
Context	All contexts; articles written in English or French

Extraction of results

We have developed a draft charting table (Table 2) to record key information from each publication or report. The extraction form will be pilot tested by each of the two primary reviewers with several studies to ensure that all relevant data is extracted and will be updated if additional relevant variables are identified.

Table 2. Data charting domains and descriptions to be used for data extraction	on
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Domain/subdomain	Description
Article details	
Article citation	Citation details of studies or report.
Article type	Study type including empirical research studies,
	case studies or program reports.
Country	Country the article is from.
Study details	
Study design	Study design of empirical research articles, or evaluation design for program reports.
Participants	Characteristics of the study or program participants.

Intervention	Description of the intervention.
Intervention mechanism	Theory of change of intervention.
Intervention structure	Detailed intervention components, delivery and facilitators.
Intervention duration	Duration of intervention
Comparison	Description of any comparison groups.
Study outcomes and measures	List of outcomes and other measures assessed in study or program evaluation.
Findings	Main results of the study.
Recommendations	Authors recommendations based on findings or experiences.

Data synthesis

We will present the search and screening flow process (Figure 1). The findings from the scoping review will be presented in a table summarizing the information of each of the included studies to highlight year of the literature, countries of origin, intervention component, and research methods, following the general format of our charting table (Table 2). Additionally, we will present participant outcomes by type of intervention component, and by fistula etiology, if possible. Narrative summaries of each of these findings will accompany the figures/tables. Two reviewers (AE and CP) will thematically analyze the data within each of the subdomains outlined in Table 2, working together to consolidate the findings through consensus. Additional content experts with knowledge of obstetric fistula in global contexts (AD, SO, JB, AK, JKB) will be available to provide guidance during this step. The text will describe how the findings of the scoping review relate to the review objective and respond to each of the specific research questions. We will then discuss our recommendations for future research and next steps.

Ethics and dissemination

No ethical review is required for a scoping review of the literature; thus, we have not sought ethics approval for our review.

The proposed scoping review will help in understanding and describing what is known and unknown about rehabilitation and social reintegration of women following genital fistula surgery. We know that as a consequence of fistula, women are often stigmatized and marginalized from their community, with high rates of depression that persist even after surgical repair. While access to surgical care has improved, there is less known about the approach to post-surgical social services, including reintegration and rehabilitation. While there is a call in the literature for the need of post-surgical reintegration services, there is a dearth of information describing best practices or detailing the specific requirements needed for a successful program.

Results from this scoping review with be useful in developing social reintegration projects in areas where fistula projects are ongoing. The results of this review can be used to inform policy and serve as support for funding and development of reintegration programs. Furthermore, the results can highlight areas or future research to pursue and help in building protocols for post-surgical rehabilitation and reintegration programs throughout contexts where fistula is prevalent.

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The study may be limited by including only articles published in English and French as study eligibility criteria and the lack of published articles on this topic. However, our scoping review will also include a systematic approach to reviewing the gray literature, in hopes of capturing all relevant information. Even in finding a deficit of published information, this scoping review may be a call for future published research in the area of social reintegration and rehabilitation of women following genital fistula surgery.

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Authors' contributions: AE, JB, SO and JBa conceived the project. AE, CP, and JBW drafted the protocol. AE, CP, AD, JBW SO, JBy, AK, and JK revised the protocol. All authors agreed upon the final protocol version.

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Competing interests statement. The authors declare no competing or conflicts of interest.

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Appendix 1. List of organizational websites identified by the Campaign to End Fistula Partners (UNFPA)²⁵ that will be searched for relevant content.

- Aden Hospital (Yemen) •
- African Medical and Research Foundation •
- American College of Nurse-Midwives •
- Babbar Ruga Fistula Hospital (Nigeria) •
- **Bangladesh Medical Association** •
- Bill & Melinda Gates Institute for Population and Reproductive Health •
- Bugando Medical Center (United Republic of Tanzania) CARE •
- Centers for Disease Control and Prevention (CDC) •
- Centre Mère-Enfant (Chad) •
- Centre National de Référence en Fistule Obstétricale (Niger) •
- Centre National de Santé de la Reproduction & du Traitement des Fistules (Chad) •
- Columbia University's Averting Maternal Death and Disability Program (AMDD) •
- Comprehensive Community Based Rehabilitation in Tanzania (CCBRT) •
- CURE International Hospital of Kabul (Afghanistan) •
- **Direct Relief International** •
- Dr. Abbo's National Fistula and Urogynaecology Center (Sudan) •
- *s*y of Obs. ۲ East Central and Southern Africa Association of Obstetrical and Gynecological Societies •
- EngenderHealth •
- Equilibres & Populations •
- Eritrea Women's Project •
- Family Care International •
- Fistula e.V. •
- **Fistula Foundation**
- Fistula Foundation Nigeria •
- Freedom from Fistula Foundation •
- Friends of UNFPA •
- Geneva Foundation for Medical Education and Research •
- Girls' Globe •
- **Governess Films** •
- Gynocare Fistula Center (Kenya)
- Hamlin Fistula (Ethiopia) ٠
- Healing Hands of Joy (Ethiopia) •
- Health and Development International
- Health Poverty Action (Sierra Leone)
- Hope Again Fistula Support Organization (Uganda) •
- Human Rights Watch
- Institut de Formation et de Recherche en Urologie et Santé de la Famille (IFRU-SF) (Senegal) •
- International Confederation of Midwives (ICM) •
- International Continence Society •
- International Federation of Gynecology and Obstetrics (FIGO) •

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4	International Forum of Research Donors (IFORD)
5	International Nepal Fellowship (INF)
6	 International Planned Parenthood Federation (IPPF)
7	 International Society of Obstetric Fistula Surgeons (ISOFS)
8	 International Urogynecological Association (IUGA)
9 10	 International Women's Health Coalition, Islamic Development Bank
11	Johns Hopkins Bloomberg School of Public Health
12	Johnson & Johnson
13	Kupona Foundation
14	
15	
16 17	• Ligue d'Initiative et de Recherche Active Pour la Santé et l'Education de la Femme (LIRASEF,
18	Cameroon)
19	London School of Hygiene and Tropical Medicine
20	Maputo Central Hospital (Mozambique)
21	Médecins du Monde
22	Médecins Sans Frontières (MSF)
23 24	Mercy Ships
25	Moi University (Kenya)
26	Monze Hospital (Zambia)
27	 Mulago Hospital/Medical School (Uganda)
28	National Obstetric Fistula Centre, Abakiliki (Nigeria)
29 30	Obstetrical and Gynecological Society of Bangladesh
31	One by One
32	Operation Fistula
33	Pakistan National Forum on Women's Health
34	 Pan African Urological Surgeons' Association (PAUSA)
35	 Population Media Center
36 37	
38	Psychology Beyond Borders
39	Regional Prevention of Maternal Mortality Network (RPMM, Ghana)
40	Royal College of Obstetricians and Gynaecologists (RCOG)
41	Sana'a Hospital (Yemen)
42 43	Selian Fistula Project (United Republic of Tanzania)
43	 Société Africaine des Gynécologues-Obstétriciens (SAGO)
45	Société Internationale d'Urologiel
46	Solidarité Femmes Africaines (SOLFA)
47	• The Association for the Rehabilitation and Re-orientation of Women for Development
48	(TERREWODE, Uganda)
49 50	Uganda Childbirth Injury Fund
51	United Nations Population Fund (UNFPA)
52	 United States Agency for International Development (USAID)
53	 University of Aberdeen
54	 University Teaching Hospital of Yaoundé (Cameroon)
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- White Ribbon Alliance
- Women and Health Alliance International (WAHA)
- Women's Health Organization International (WHOI)
- Women's Hope International (WHI)
- Women's Missionary Society of the African Methodist Episcopal Church
- World Health Organization (WHO)
- World Vision
- Worldwide Fistula Fund
- Zonta International

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Name of database	Search strategy
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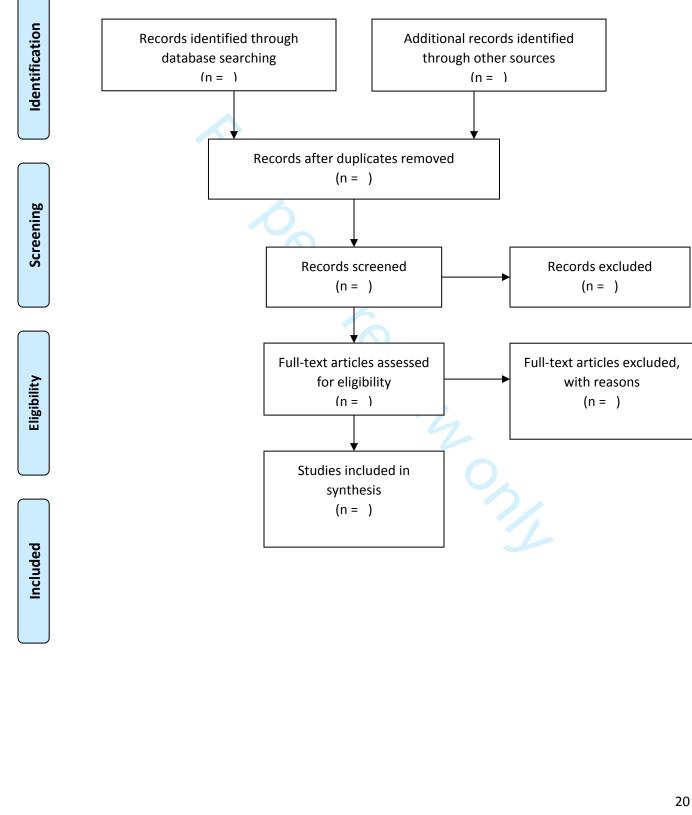
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Fig 1. PRISMA flowchart for selection of eligible studies and program reports.^{17 26}



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Rehabilitation and Reintegration Programming Adjunct to Female Genital Fistula Surgery: A Scoping Review Protocol

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Primary Subject Heading :	Global health
Secondary Subject Heading:	Health services research
Keywords:	female genital fistula, supportive care, reintegration, rehabilitation, scoping review

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3	1	Title: Rehabilitation and Reintegration Programming Adjunct to Female Genital Fistula Surgery: A Scoping
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5	2	Review Protocol
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Abstract

Introduction

Female genital fistula is a debilitating traumatic injury, largely birth-associated, globally affecting up to 2 million women, mostly in sub-Saharan Africa. Fistula has significant physical, psychological, and economic consequences. Women often face challenges in reintegrating and resuming prior roles despite successful surgery. Synthesizing the evidence on services adjunct to fistula surgery and their outcomes is important for developing the evidence base for best practices and identifying research priorities. This scoping review seeks to examine the range of rehabilitation and reintegration services provided as adjunct to genital fistula surgery, map the existing programming and outcomes, and identify areas for additional research.

Methods and analysis

Our scoping review is informed by existing methodological frameworks and will be conducted in accordance with PRISMA-ScR guidelines. The search strategy will be applied to nine biomedical, public health, and social science databases. The initial search was completed on September 27, 2018. Grey literature will be identified through targeted Google searches and from organizational websites identified as relevant by the UNFPA Campaign to End Fistula. We will iteratively build our search strategy through term harvesting and review, and search reference lists of reports and articles to identify additional studies. Two reviewers will independently screen titles and abstracts, followed by full-text screening of all potentially relevant articles and standardized data extraction. Articles eligible for inclusion will discuss research or programmatic efforts around service provision in adjunct to surgery among females with genital fistula. Data will be presented in summary tables accompanied by narrative description.

Ethics and dissemination

Ethics approval is not required for a scoping review. Our results can be used to inform policy, serve as support for funding and development of reintegration programs, and highlight areas for subsequent research. Results will be disseminated at relevant conferences and published in a peer-reviewed journal.

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3	73	Article Summary:
4	74	1. No systematic efforts have been previously carried out to map the rehabilitation and reintegration
5	75	services provided in adjunct to female genital fistula surgery despite recognition in the literature
6 7	76	of significant physical, psychosocial, and economic sequelae of the condition.
8	77	2. Our scoping review utilizes an established framework, employs a comprehensive search strategy
9	78	developed iteratively in conjunction with a medical librarian, and study selection and extraction
10	79	will be undertaken by content experts.
11	80	3. Compiling the evidence on existing programs and outcomes will inform the development of
12	81	evidence-based public health strategies for supporting women recovering from female genital
13	82	fistula and inform the measurement of impact of such strategies.
14	83	4. No formal assessment of the quality of studies will be conducted, as the goal of a scoping review
15	84	is to map the range of evidence on a particular topic.
16	85	5. The findings of this scoping review will be limited to articles and program reports published in
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18		English or French.
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20 21	88	Keywords: female genital fistula, supportive care, reintegration, rehabilitation, scoping review
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Introduction

Female genital fistula is a debilitating and traumatic injury that affects an estimated 2 million women, mostly in sub-Saharan Africa¹. Primarily due to prolonged and neglected obstructed labor from cephalopelvic disproportion or malpresentation combined with delays in accessing comprehensive emergency obstetric care, up to 100,000 new cases occur each year globally. During the obstructed labor, ischemia from compression of soft vaginal, bladder or rectal tissue between the fetal head and pelvic bone results in ischaemic necrosis, and a fistula is formed upon sloughing of this tissue². Women with fistula experience uncontrollable leakage of urine and/or feces, which contributes to the development of genital sores and infection ^{3,4}. In addition to pain and general weakness⁵, women may experience nerve damage, uterine cervix injuries and pelvic bone trauma which present as secondary infertility and gait disorders⁶. For most deliveries resulting in fistula, the baby does not survive⁷. Women with fistula are often stigmatized and marginalized from their families and communities and live in isolation, unable to participate in social, economic, food preparation or religious activities^{5,7}, and report high psychiatric morbidity including depression, which may persist after surgery⁸⁻¹⁰.

Access to obstetric fistula surgery has improved in sub-Saharan Africa overall; however, despite having undergone surgical repair, women may continue to face myriad physical and psychological challenges to resuming their previous roles or adjusting to new circumstances. They may also require further medical care depending on the severity of their injuries and surgical outcomes and require health care access for subsequent pregnancies and births. Longitudinal studies from sub-Saharan Africa have identified risks of adverse outcome following fistula surgery, including fistula recurrence, persistent fistula-related symptoms, subsequent fertility challenges, and adverse perinatal outcomes¹¹⁻¹³. In Guinea, for example, the cumulative incidence of fistula recurrence was 16% at 24 months¹³. In Uganda, by twelve-months post-surgery, one-third of women continued to experience urinary incontinence, 17% reported weakness, and 9% reported general pain¹⁴. In Malawi, only one-fifth of women with reproductive potential were able to become pregnant in the year following surgery¹². Furthermore, experience of persistent physical symptoms or adversity is associated with substantially lower psychosocial health¹⁴. All of these factors limit women's ability to resume their previous roles despite successful surgery, particularly in the context of economic hardship¹⁵. A systematic review of ten gualitative studies from sub-Saharan Africa identified various reintegration needs from the perspectives of both women affected by fistula and health professionals working with this patient population, including health education and counselling¹⁶.

This literature highlights the need for post-surgical reintegration and rehabilitation services; however, there remains a knowledge and practice gap around programming to best assist women to reintegrate into their families and communities after surgery. Preliminary evidence from Nigeria and Eritrea supports short-term facility-based psychological intervention for improving women's mental health^{17,18}, and programming supported by non-governmental organizations often includes counseling, physical therapy, and skills training. Synthesizing research on the reintegration process, evaluation, and service provision is of paramount importance to develop a strong evidence base, which can guide prioritization of service provision to meeting the future health needs of women who have experienced obstetric fistula.

Thus, the objective of this scoping review is to examine the range of rehabilitation and reintegration services provided as adjunct to genital fistula surgery, map the existing programming and outcomes, and identify areas where additional research is necessary.

Methods and analysis

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2		
3	139	The purpose of this scoping review is to understand the extent to which rehabilitation and reintegration
4	140	services have been provided to women in conjunction with female genital fistula surgery and the
5	141	outcomes of such programming. The findings from this review will be used to support the evidence-based
6	142	development of programming for women undergoing surgery for female genital fistula surgery and
7 8	143	identify further research needs in this area. A preliminary search for existing reviews on this topic has
8 9	144	been conducted in JBISIR, PROSPERO, PubMed, Cochrane Database of Systematic Reviews, EPPI, and
10	145	Epistemonikos, and no similar systematic or scoping reviews were identified. Given the lack of prior
11	146	reviews, a scoping review is an appropriate first step to assessing the literature in this area. Our scoping
12	147	review methodology is informed by the Arskey & O'Malley ¹⁹ and Levac ²⁰ frameworks and will be
13	148	conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses
14	149	(PRISMA-ScR) guidelines. ²¹
15	150	
16	151	Patient and Public Involvement
17 18	152	Patients and or/public were not involved in the design or development of this protocol and research
19	153	questions. Results of this study will not be disseminated to study participants.
20	154	
21	155	Identifying the Research Question
22	156	The objective of this scoping review is to examine the range of rehabilitation and reintegration services
23	157	provided as adjunct to genital fistula surgery, map the existing programming and outcomes of
24	158	programming, and identify areas where additional research is necessary. To achieve these objectives, our
25	159	review targets the following research questions:
26 27	160	1. What rehabilitation and reintegration services are provided as adjunct to genital fistula surgery
27	161	for women with obstetric, iatrogenic, or traumatic fistula?
29	162	2. What are the components of each rehabilitation and reintegration intervention, and how are they
30	163	delivered?
31	164	3. What is the impact of each rehabilitation and reintegration intervention on women's physical,
32	165	psychosocial, and economic status?
33	166	4. What are the authors' recommendations for rehabilitation and reintegration interventions and
34 35	167	intervention delivery?
36	168	5. What are the areas of research gaps and what topics should future research focus on?
37	169	
38	170	In this review, we include genital fistula from obstetric, iatrogenic, and traumatic etiologies. Obstetric
39	171	refers to fistula resulting from pressure necrosis due to prolonged obstructed labor; iatrogenic refers to
40	172	fistula resulting from surgical error, primarily occurring during cesarean section or hysterectomy; and
41	173	traumatic refers to those fistula resulting from sexual assault.
42	174	
43 44	175	Types of Sources
45	176	Sources to be reviewed include biomedical, public health, and social science databases, including PubMed,
46	177	Embase, Popline, PsycINFO, Web of Science, Sociological Abstracts, Social Services Abstracts, and African
47	178	Journals Online, the grey literature identified within targeted Google searches and directly from
48	179	organization websites identified as being relevant by the Campaign to End Fistula Partners (UNFPA)
49	180	(Appendix 1), and through personal queries with clinical and social service organizations working in fistula
50	181	research. All data and articles will be managed within Endnote citation software.
51 52	182	
52 53	183	Search Strategy
54	184	We will employ a three-step search strategy for identifying published and unpublished studies for our
55	185	scoping review. An initial search was performed on September 27, 2018.
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We will begin by conducting a preliminary search of PubMed to identify key articles on our topic and begin the process of term harvesting, described herein. From these key articles, we will extract text words and MeSH terms from titles, abstracts, and author-supplied keywords to build a comprehensive list of keywords and controlled vocabulary terms, to inform our search strategy development. Next, we will work collaboratively with a medical librarian (JBW) with training and experience in systematic reviews to design our search strategy using an iterative process that follows an established search method²². Each potential search term will be tested, with the two primary reviewers examining the first 60 unique results for each term in order to determine that term's relevance and subsequent inclusion in the search strategy. The search strategy will be developed in PubMed and adapted to other databases accordingly, using controlled vocabulary (e.g. MeSH, Emtree, thesaurus terms) where databases allow. A second librarian will peer review the final search strategy using the Peer Review of Electronic Search Strategies (PRESS) guidelines.²³

Thirdly, the reference lists of all included reports and articles will be searched to identify any additional studies. The reviewers will contact authors of primary studies, reviews, and grey literature if further information is desired.

The search strategy will combine two main concepts: obstetric fistula and social reintegration. Boolean logic will be applied by combining similar key words and controlled vocabulary (e.g. MeSH and Emtree terms) with OR and using AND between the two concepts, for example, ("obstetric fistula" OR "vesicovaginal fistula") AND (reintegration OR rehabilitation). During preliminary searching, we have found a large number of, irrelevant articles related to cancer in two sets of database 31% of our results in Embase and 17% of our results in Web of Science); therefore, an additional concept using cancer-related terms will be added using the NOT term that will exclude these terms from our searches in those two databases. To ensure that this concept exclusion will not eliminate any relevant results, the primary reviewers evaluated the first 100 unique results that would be left out of searches that used this NOT concept. No relevant articles were discovered using this method; thus, we feel confident that this technique will only exclude irrelevant articles. The complete search strategy for all databases can be found in Appendix 2.

In accordance with PRISMA guidelines, no language limits will be used in the search. Date limits will be applied to identify relevant studies as social reintegration for obstetric fistula is a reasonably new area of study. To determine which date limits to use, primary reviewers tested searches from various publication date ranges, looking through the first 50 unique results of each time span to judge relevance of the studies included in these dates. Using this method, we chose to include articles from 2000 through 2018.

Study selection

Two primary reviewers (AE & CP) will independently screen titles and abstracts of all articles, followed by full-text screening and data extraction. A third reviewer (AD) will be available to resolve discrepancies and will ultimately determine if the study meets inclusion criteria for data extraction Study screening progress will be documented in a modified PRISMA flow chart (Figure 1). In accordance with established scoping review frameworks, 19,20 critical appraisal of study quality will not be performed owing to the heterogeneity of results and the multi-tiered aspect of the research question.

Inclusion and Exclusion Criteria

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- Inclusion and exclusion criteria for selection of eligible studies were developed using the population,
- concept, context elements proposed for scoping reviews by the Joanna Briggs Institute (Table 1).²⁴ We selected this approach in order to broadly identify all data that is potentially relevant to our objective.
- Types of participants
- Females diagnosed with genital fistula with obstetric, iatrogenic (non-cancer), or traumatic etiology and accessing surgical treatment. No limitations on geography or age will be placed.
- Concept

- Research or service provision for all services provided in adjunct to surgery among females diagnosed with genital fistula of obstetric, iatrogenic (non-cancer), or traumatic etiology. Interventions of interest are anticipated to include but will not be limited to the following: psychological therapy, physical therapy, skills training or other economic empowerment.
- The scoping review will be heavily focused on the services provided; however, we will capture any clinical or patient-reported outcomes beyond surgical success including but not limited to: persistent incontinence, pain, weakness, difficulty walking, quality of life, depressive symptoms, self-esteem, relationship stability, and stigma.
 - Context
- No contextual limitations will be placed on the scoping review; however, we are unable to review articles written in languages other than English and French. Due to the geographic distribution of female genital fistula, we anticipate that the majority of the evidence will originate in sub-Saharan Africa.

Table 1. Population, Concept, Context for Identification of Eligible Studies

Criteria	Description
Population	Females undergoing surgery for genital fistula
	Fistula etiologies: obstetric, iatrogenic (non-cancer), traumatic
	All ages
Concept Any research or service provision in addition to surgery; no limitations or	
	type
	Clinical or patient-reported outcomes beyond surgical success
	Studies or reports including original research or program data
Context	All contexts; articles written in English or French

Extraction of results

We have developed a draft charting table (Table 2) to record key information from each publication or report. The extraction form will be pilot tested by each of the two primary reviewers with several studies to ensure that all relevant data is extracted and will be updated if additional relevant variables are identified.

Table 2. Data charting domains and descriptions to be used for data extraction

[Domain/subdomain	Description
	Article details	
	Article citation	Citation details of studies or report.

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Article type	Study type including empirical research studies,
	case studies or program reports.
Country	Country the article is from.
Study details	
Study design	Study design of empirical research articles, or evaluation design for program reports.
Participants	Characteristics of the study or program participants.
Intervention	Description of the intervention.
Intervention mechanism	Theory of change of intervention.
Intervention structure	Detailed intervention components, delivery and facilitators.
Intervention duration	Duration of intervention
Comparison	Description of any comparison groups.
Study outcomes and measures	List of outcomes and other measures assessed in study or program evaluation.
Findings	Main results of the study.
Recommendations	Authors recommendations based on findings or experiences.

265 Data synthesis

266 We will present the search and screening flow process (Figure 1). The findings from the scoping review 267 will be presented in a table summarizing the information of each of the included studies to highlight year of the literature, countries of origin, intervention component, and research methods, following the 268 269 general format of our charting table (Table 2). Additionally, we will present participant outcomes by type 270 of intervention component, and by fistula etiology, if possible. Narrative summaries of each of these 271 findings will accompany the figures/tables. Two reviewers (AE and CP) will thematically analyze the data 272 within each of the subdomains outlined in Table 2, working together to consolidate the findings through 273 consensus. Additional content experts with knowledge of obstetric fistula in global contexts (AD, SO, JB, 274 AK, JKB) will be available to provide guidance during this step. The text will describe how the findings of 275 the scoping review relate to the review objective and respond to each of the specific research questions. 276 We will then discuss our recommendations for future research and next steps.

277 Ethics and dissemination

No ethical review is required for a scoping review of the literature; thus, we have not sought ethics approval for our review.

282 The proposed scoping review will help in understanding and describing what is known and unknown about 283 rehabilitation and social reintegration of women following genital fistula surgery. We know that as a 50 284 consequence of fistula, women are often stigmatized and marginalized from their community, with high 51 285 rates of depression that persist even after surgical repair. While access to surgical care has improved, 52 286 there is less known about the approach to post-surgical social services, including reintegration and 53 54 rehabilitation. While there is a call in the literature for the need of post-surgical reintegration services, 287

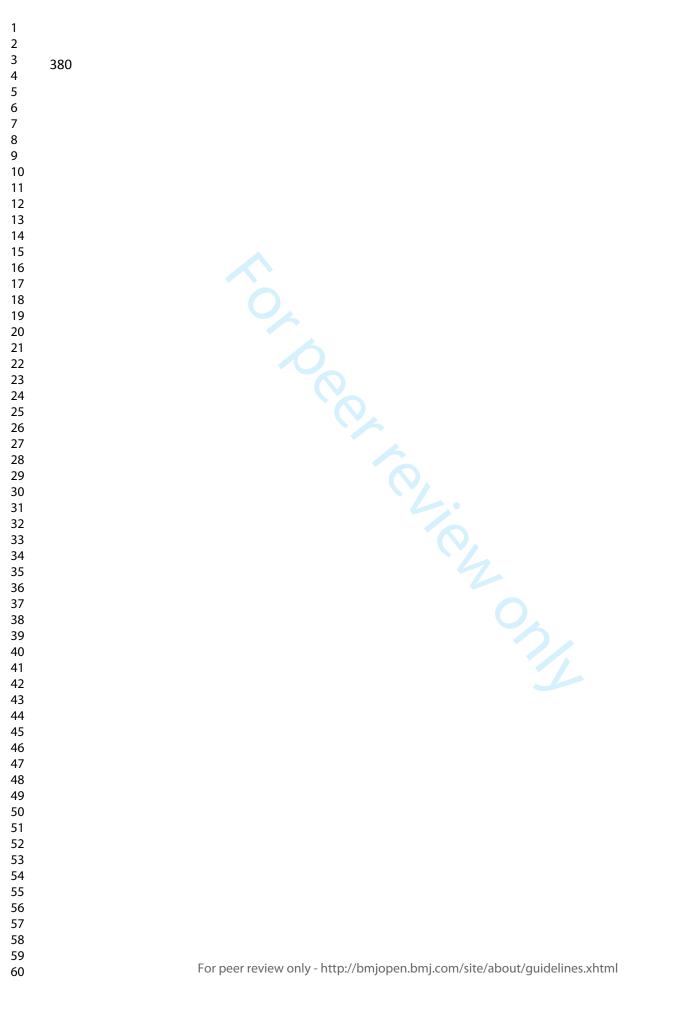
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2 3 4 5	288 289	there is a dearth of information describing best practices or detailing the specific requirements needed for a successful program.
6	290 291	Results from this scoping review with be useful in developing social reintegration projects in areas where
7	292	fistula projects are ongoing. The results of this review can be used to inform policy and serve as support
8 9	292	for funding and development of reintegration programs. Furthermore, the results can highlight areas or
10	295 294	
11		future research to pursue and help in building protocols for post-surgical rehabilitation and reintegration
12	295	programs throughout contexts where fistula is prevalent.
13	296	The study may be limited by including only articles published in English and French as study eligibility
14	297	criteria and the lack of published articles on this topic. However, our scoping review will also include a
15 16	298	systematic approach to reviewing the gray literature, in hopes of capturing all relevant information. Even
17	299	in finding a definit of published information, this scening ravious may be a call for future published research
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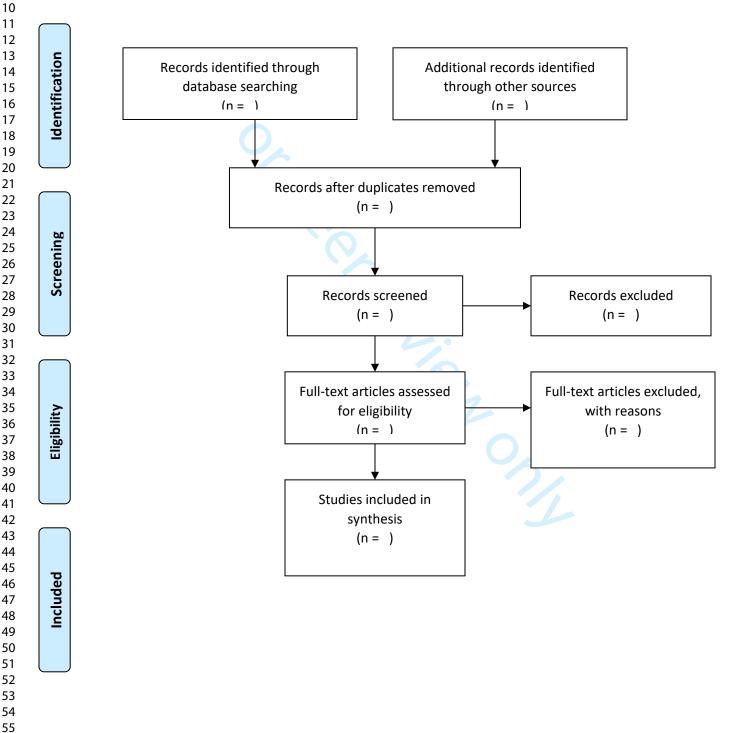
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4	351	science : IS 2010; 5 : 69.
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6	353	and Explanation. Annals of internal medicine 2018; 169 (7): 467-73.
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9 10	356	23. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of
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12		Electronic Search Strategies: 2015 Guideline Statement. <i>J Clin Epidemiol</i> 2016; 75 : 40-6.
13	358	24. The Joanna Briggs Institute. Joanna Briggs Institute Reviewers' Manual: 2015 edition/supplement.
14	359	Adelaide: The Joanna Briggs Institute, 2015.
15	360	
16	361	Authors' contributions: AE, JBy, SO and JBa conceived the project. AE, CP, and JBW drafted the protocol.
17	362	AE, CP, AD, JBW SO, JBy, AK, and JBa revised the protocol. All authors agreed upon the final protocol
18	363	version.
19	364	
20		Funding statements This work will be supported in part by the Eurise Kennedy Shriver National Institute
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22	366	of Child Health and Human Development grant number R00HD086232.
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24 25	368	Competing interests statement. The authors declare no competing or conflicts of interest.
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26 27	370	Figures
28	371	Figure 1. PRISMA flowchart for selection of eligible studies and program reports.
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30	373	Supplemental files (Appendix):
31	374	Appendix 1. List of organizational websites identified by the Campaign to End Fistula that will be
32	375	searched for relevant content.
33	376	Appendix 2: Search strategy for all databases
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Supplemental Files: Figures

Manuscript: Rehabilitation and Reintegration Programming Adjunct to Female Genital Fistula Surgery: A Scoping Review Protocol

Fig 1. PRISMA flowchart for selection of eligible studies and program reports.^{17 26}



Supplemental Files: Appendices

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Appendix 1. List of organizational websites identified by the Campaign to End Fistula Partners (UNFPA)²⁵ that will be searched for relevant content.

- Aden Hospital (Yemen)
- African Medical and Research Foundation
- American College of Nurse-Midwives
- Babbar Ruga Fistula Hospital (Nigeria)
- Bangladesh Medical Association
- Bill & Melinda Gates Institute for Population and Reproductive Health
- Bugando Medical Center (United Republic of Tanzania) CARE
- Centers for Disease Control and Prevention (CDC)
- Centre Mère-Enfant (Chad)
- Centre National de Référence en Fistule Obstétricale (Niger)
- Centre National de Santé de la Reproduction & du Traitement des Fistules (Chad)
- Columbia University's Averting Maternal Death and Disability Program (AMDD)
- Comprehensive Community Based Rehabilitation in Tanzania (CCBRT)
- CURE International Hospital of Kabul (Afghanistan)
- Direct Relief International
- Dr. Abbo's National Fistula and Urogynaecology Center (Sudan)
- East Central and Southern Africa Association of Obstetrical and Gynecological Societies
- EngenderHealth
- Equilibres & Populations
- Eritrea Women's Project
- Family Care International
- Fistula e.V.
- Fistula Foundation
- Fistula Foundation Nigeria
- Freedom from Fistula Foundation
- Friends of UNFPA
- Geneva Foundation for Medical Education and Research
- Girls' Globe
- Governess Films
- Gynocare Fistula Center (Kenya)
- Hamlin Fistula (Ethiopia)
- Healing Hands of Joy (Ethiopia)
- Health and Development International
- Health Poverty Action (Sierra Leone)
- Hope Again Fistula Support Organization (Uganda)
- Human Rights Watch

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3 4	Institut de Formation et de Recherche en Urologie et Santé de la Famille (IFRU-SF) (Senegal)
5	 International Confederation of Midwives (ICM)
6	International Continence Society
7	 International Federation of Gynecology and Obstetrics (FIGO)
8	International Forum of Research Donors (IFORD)
9 10	International Nepal Fellowship (INF)
10	International Planned Parenthood Federation (IPPF)
12	International Society of Obstetric Fistula Surgeons (ISOFS)
13	 International Urogynecological Association (IUGA)
14	 International Women's Health Coalition, Islamic Development Bank
15 16	 Johns Hopkins Bloomberg School of Public Health
17	 Johnson & Johnson
18	
19	Kupona Foundation
20	Lake Tanganyika Floating Health Clinic
21	• Ligue d'Initiative et de Recherche Active Pour la Santé et l'Education de la Femme (LIRASEF,
22 23	Cameroon)
24	London School of Hygiene and Tropical Medicine
25	Maputo Central Hospital (Mozambique)
26	Médecins du Monde
27	Médecins Sans Frontières (MSF)
28 29	Mercy Ships
30	Moi University (Kenya)
31	Monze Hospital (Zambia)
32	Mulago Hospital/Medical School (Uganda)
33	National Obstetric Fistula Centre, Abakiliki (Nigeria)
34	Obstetrical and Gynecological Society of Bangladesh
35 36	One by One
37	Operation Fistula
38	 Pakistan National Forum on Women's Health
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41 42	Population Media Center
43	Psychology Beyond Borders
44	Regional Prevention of Maternal Mortality Network (RPMM, Ghana)
45	 Royal College of Obstetricians and Gynaecologists (RCOG)
46	Sana'a Hospital (Yemen)
47 48	 Selian Fistula Project (United Republic of Tanzania)
48	 Société Africaine des Gynécologues-Obstétriciens (SAGO)
50	Société Internationale d'Urologiel
51	Solidarité Femmes Africaines (SOLFA)
52	• The Association for the Rehabilitation and Re-orientation of Women for Development
53	(TERREWODE, Uganda)
54 55	Uganda Childbirth Injury Fund
56	 United Nations Population Fund (UNFPA)
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- United States Agency for International Development (USAID)
- University of Aberdeen
- University Teaching Hospital of Yaoundé (Cameroon)
- Virgin Unite

- White Ribbon Alliance
- Women and Health Alliance International (WAHA)
- Women's Health Organization International (WHOI)
- Women's Hope International (WHI)
- Women's Missionary Society of the African Methodist Episcopal Church
- World Health Organization (WHO)
- World Vision
- Worldwide Fistula Fund
- Zonta International

Appendix 2. Search strategy for all databases. All searches will be limited to 2000-present.

Name of database	Search strategy				
PubMed	 "vaginal fistulae"[tiab] OR "vesicovaginal fistula"[tiab] OR "vesicovaginal fistulae"[tiab] OR "vesicovaginal fistulas"[tiab] OR "ureterovaginal fistula"[tiab] OR "ureterovaginal fistula"[tiab] OR "ureterovaginal fistula"[tiab] OR "ureterovaginal fistulas"[tiab] OR "bladder fistulas"[tiab] OR "cystocolic fistulas"[tiab] OR "cystocolic fistulae"[tiab] OR "cystocolic fistulae"[tiab] OR "cystovaginal fistulas"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistula"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistula"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistula"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistulas"[tiab] OR "ureter fistula"[tiab] OR "ureter fistula"[tiab] OR "ureter fistulae"[tiab] OR "ureter fistulas"[tiab] OR "ureter fistulas"[tiab] OR "ureter fistulae"[tiab] OR "ureter fis				
Embase	"Self Care"[Mesh] OR "Self-Management"[Mesh] OR training[tiab] Of mobility[tiab] OR independence[tiab] OR decision-making[tiab] Of respect[tiab]) (('obstetric fistula':ab,ti OR 'obstetric fistulae':ab,ti OR 'vaginal fistula':ab,ti OR				
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	NOT (cancer:ab,ti OR 'neoplasm'/exp OR prostate:ab,ti OR 'prostate'/exp O hypospadia:ab,ti OR 'hypospadias'/exp OR penile:ab,ti OR transgender:ab OR 'gender confirming':ab,ti)
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	AND (rehabilitation OR "quality of life" OR reintegration OR rehabilitating O reintegrating OR reintegrated OR counseling OR exercise OR exercises O education OR physiotherapy OR knowledge OR "self esteem" OR "ment health" OR "mental well-being" OR psychological OR behavioral OR coping O depression OR anxiety OR suicidal OR suicide OR distress OR stress OR soci OR recovery OR "skills training" OR "gender-based" OR power OR empower OR empowered OR empowerment OR livelihood OR microfinance O financial OR finance OR "self help" OR "self-help" OR training OR mobility O independence OR decision-making OR respect OR socioeconomic)
PsycINFO	("obstetric fistula" OR "obstetric fistulae" OR "vaginal fistula" OR "vaginal fistulae" OR "vesicovaginal fistula" OR "vesicovaginal fistulae" OR "vesico-vagin fistula" OR "vesico-vaginal fistulae" OR "obstetric fistulas" OR "vagin fistulas" OR "vesicovaginal fistulas" OR "vesico-vaginal fistulas" O "ureterovaginal fistula" OR "rectovaginal fistula" OR "genital tract fistula" O "urinary fistula" OR "uro-vaginal fistula" OR "recto-vaginal fistula" O

	"ureterovaginal fistulae" OR "rectovaginal fistulae" OR "genital tract fistulae OR "urinary fistulae" OR "uro-vaginal fistulae" OR "recto-vaginal fistulae" OR "ureterovaginal fistulas" OR "rectovaginal fistulas" OR "genital tract fistula OR "urinary fistulas" OR "uro-vaginal fistulas" OR "recto-vaginal fistulas" OR "urinary fistulas" OR "uro-vaginal fistulas" OR "recto-vaginal fistulas" OR "urinary fistulae" OR "bladder fistulae" OR "bladder fistulae" OR "bladder fistulae" OR "bladder fistulae" OR "cystocolic fistulae" OR "cystovaginal fistulae" OR "cystovaginal fistulae" OR "cystovaginal fistulae" OR "cystovaginal fistulae" OR "ureter fistulae" OR "urethra fistulae" OR "ur
	AND
	(rehabilitation OR "quality of life" OR reintegration OR rehabilitating reintegrating OR reintegrated OR counseling OR exercise OR exercises education OR physiotherapy OR knowledge OR "self esteem" OR "men health" OR "mental well-being" OR psychological OR behavioral OR coping depression OR anxiety OR suicidal OR suicide OR distress OR stress OR soc OR recovery OR "skills training" OR "gender-based" OR power OR empowe OR empowered OR empowerment OR livelihood OR microfinance financial OR finance OR "self help" OR "self-help" OR training OR mobility independence OR decision-making OR respect MAINSUBJECT.EXACT("Quality of Life") MAINSUBJECT.EXACT("Interpersonal Control"))
Sociological Abstracts & Social Services Abstracts	
	AND
	(rehabilitation OR "quality of life" OR reintegration OR rehabilitating reintegrating OR reintegrated OR counseling OR exercise OR exercises education OR physiotherapy OR knowledge OR "self esteem" OR "men health" OR "mental well-being" OR psychological OR behavioral OR coping depression OR anxiety OR suicidal OR suicide OR distress OR stress OR soc

1 2		
3 4 5 6 7 8 9 10 11		OR recovery OR "skills training" OR "gender-based" OR power OR empower OR empowered OR empowerment OR livelihood OR microfinance OR financial OR finance OR "self help" OR "self-help" OR training OR mobility OR independence OR decision-making OR respect OR MAINSUBJECT.EXACT("Power") OR MAINSUBJECT.EXACT("Empowerment") OR MAINSUBJECT.EXACT("Social Power") OR MAINSUBJECT.EXACT("Quality of Life") OR MAINSUBJECT.EXACT("Rehabilitation"))
12 13 14 15 16	African Journals Online	fistula AND (rehabilitation OR reintegration OR education OR empowerment OR empower OR "self help" OR "quality of life" OR recovery OR reintegrated OR reintegrating OR power OR training OR coping OR mental OR decision OR counseling OR distress OR social)
$\begin{array}{c} 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 39\\ 40\\ 41\\ 42\\ 43\\ 34\\ 45\\ 46\\ 47\\ 48\\ 49\\ 50\\ 51\\ 52\\ 53\\ 54\\ 55\\ 56\\ 57\\ 58\\ 59\\ 60\\ \end{array}$		iew only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
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PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	ш	Checklist item	Information reported		Line	
	#		Yes	No	number(s)	
ADMINISTRATIVE IN	FORMAT	ION				
Title						
Identification	1a	Identify the report as a protocol of a systematic review	X		2 (title) Line 52	
Update	1b	If the protocol is for an update of a previous systematic review, identify as such		X		
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract				
Authors	•		•			
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x		Line 4-38	
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	X		Line 361-363	
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments		Х		
Support						
Sources	5a	Indicate sources of financial or other support for the review	X		Line 365-366	
Sponsor	5b	Provide name for the review funder and/or sponsor	X		Line 365-366	
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol		X		
INTRODUCTION						
Rationale	6	Describe the rationale for the review in the context of what is already known	X		Line 127-129	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	X		Line 136-138	
METHODS	<u>I</u>		I	1	1	



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Saation/tania	#	Checklist item	Information reported		Line	
Section/topic			Yes	No	number(s)	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	X		Line 253	
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	X		Line 173-179	
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	X		Appendix 2 (line 466)	
STUDY RECORDS					•	
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review		X	Line 179	
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	X		Line 221-222	
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	X		Line 268-269	
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	X		Line 256-259 Table 2	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	X		Table 2	
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	X		Line 222 and 270-271	
DATA					•	
	15a	Describe criteria under which study data will be quantitatively synthesized		X		
Synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., <i>I</i> ² , Kendall's tau)		X		
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta- regression)		X		
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X		Line 263-273	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)		X		
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)		X	Line 224-225	

